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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,006	07/24/2001	Donald Shannon	VAS-4761CONDIV	5855

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Edwards Lifesciences LLC
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EXAMINER

ROSSI, JESSICA

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,006

Applicant(s)

SHANNON ET AL.

Examiner

Jessica L. Rossi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 12-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to a radially expandable tubular vascular graft, classified in class 606, subclass 194.
 - II. Claims 12-22, drawn to a radially expandable tubular vascular graft, classified in class 606, subclass 194.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an expanded base graft to be combined with the expanded reinforcing tape prior to radial shrinking of the tape. The subcombination has separate utility as a vascular graft, as evidenced by present claim 12.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Mr. Peter Gluck on 11/8/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-22 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it recites the limitation "the combined" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change it to --a combined--.

Regarding claim 5, it recites the limitation "the inside diameter" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change it to --an inside diameter--.

Regarding claim 6, it recites the limitation "the inside diameter" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change it to --an inside diameter--.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 7-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art in the specification of the present application in view of House et al. (US 5026513).

With respect to claim 1, the Admitted Prior Art in the specification of the present application teaches it is known in the art to produce vascular grafts from an expanded, sintered tubular PTFE base graft wrapped with an expanded, sintered PTFE reinforcing tape (page 1, lines 19-32). The Admitted Prior Art also notes that the tape is less stretchable after sintering making it difficult to expand the base graft around which the tape is wrapped thereby not meeting the needs of certain endovascular procedures (page 2, lines 5-21). However, the Admitted Prior Art is silent as to the base graft and tape being radially reduced in size.

House et al., directed to making recoverable PTFE materials that can be used in vascular prosthesis, teaches that expanded, sintered PTFE articles subjected to compressive forces may be recoverable by compressing in a direction opposite to that which they were expanded (column 2, lines 1-11; column 3, lines 3-5 and 25-27 and 50-53; column 4, lines 4-16 and 62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to radially compress (reduce) the PTFE graft of the Admitted Prior Art as taught by House et al. in order to provide a recoverable/re-expandable PTFE graft.

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Regarding claim 2, the Admitted Prior Art is silent as to how expansion of the base graft is achieved and in what direction this expansion takes place. It would have been obvious to one of ordinary skill in the art at the time the invention was made to longitudinally expand the base graft of the Admitted Prior Art because such is known in the art, as taught by House et al. (column 2, line 67 – column 3, line 2), and only the expected results would have been achieved. Selection of a particular method of expansion would have been within purview of one of ordinary skill in the art at the time the invention was made because only the expected results would have been achieved; it being noted that these are article claims where the method makes no difference unless one of ordinary skill can show that expansion via heating would result in a materially different product.

Regarding claim 3, the Admitted Prior art is silent as to when sintering of the base graft takes place with respect to the expansion step. It would have been obvious to one of ordinary skill in the art at the time the invention was made to sinter the base graft following expansion of the base graft but prior to its being radially reduced in size because such is known in the art, as taught by House et al. (column 3, lines 3-5 and 24-26) and radially reducing the base graft after sintering allows the base graft to be re-expanded (column 2, lines 1-11).

Regarding claim 4, House et al. teaches compressing the expanded, sintered PTFE material by heating to a sintering temperature (column 3, lines 50-52).

Regarding claims 7-8, selection of a particular compressed (reduced) diameter for the base graft would have been within purview of one of ordinary skill in the art at the time the invention was made.

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Regarding claim 11, the Admitted Prior Art is silent as to a reinforcing filament wound around the tape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to wrap a reinforcing filament around the tape because such is well known in the art for strengthening the tape.

10. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art and House et al. as applied to claim 1 above, and further in view of Dawson (US 3939243).

Regarding claim 5, the Admitted Prior Art teaches it is known to use mandrels for processing grafts. House et al. teaches heating to a sintering temperature to compress/reduce the PTFE material (column 3, lines 50-52).

Regarding claim 6, the Admitted Prior Art as modified is silent as to the base graft and tape being radially reduced in size by positioning them around a series of progressively smaller cylindrical mandrels having an outside diameter smaller than an inside diameter of the base graft. Dawson, directed to treating plastic material such as PTFE tubes, teaches that radially shrinking plastic tubing incrementally produces tubes that will expand radially without extension in length (column 1, lines 40-65; column 4, lines 45-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use incrementally sized mandrels to radially reduce the graft of the Admitted Prior Art, as taught by Dawson, to produce grafts capable of expanding radially without extension in length. House et al. teaches heating to a sintering temperature to compress/reduce the PTFE material (column 3, lines 50-52).

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11. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Admitted Prior Art and House et al. as applied to claim 1 above, and further in view of Schmitt et al. (US 6299636).

Regarding claims 9-10, the Admitted Prior Art teaches it is known to anchor the graft to a vascular wall (page 2, line 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an anchoring mechanism, such as a stent, coupled to the graft because such is known in the art, as taught by Schmitt et al. (column 1, lines 33-40), wherein the stent serves to anchor the graft to the wall.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **703-305-5419**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball can be reached on 703-308-2058. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jessica L. Rossi
Patent Examiner
Art Unit 1733



jlr
November 19, 2001



JEFF H. AFERGO
PRIMARY EXAMINER
GROUP 1300